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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,988	07/25/2005	Dieter Scharnweber	17P21PCT/US	3213

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EXAMINER
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KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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03/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,988	<b>Applicant(s)</b> SCHARNWEBER ET AL.	
	<b>Examiner</b> Young J. Kim	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) 37-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/29/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The present Office Action is responsive to the Amendment received on November 28, 2007.

#### ***Preliminary Remark***

Claims 1-22 are canceled.

Claims 23-44 are pending, of which 37-44 remain withdrawn as being drawn to non-elected invention with traverse.

#### ***Information Disclosure Statement***

The IDS received on November 29, 2007 is acknowledged.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 24 and 26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on August 28, 2007 is withdrawn in view of the Amendment received on November 28, 2007.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 23-30, 32, 33, 35, and 36 under 35 U.S.C. 102(b) as being anticipated by Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990), made in the Office Action mailed on August 28, 2007 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on November 28, 2007 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

Bitner discloses a solid support comprising an amount of metal oxide (thus metallic object comprising a coating that is comprised of thin metal oxide layer; see page 3, line 20; page 4, line 16; page 7, lines 15-16), and nucleic acid molecules having their 5'- terminal or 3'- terminal ends incorporated into said metal oxide layer (page 3, lines 22-23), clearly anticipating claim 23.

With regard to claim 24, the nucleic acids retain their biological accessibility and reactivity, such as for hybridization (page 5, lines 10-13).

With regard to claims 25 and 26, the artisan discloses that the phosphate backbones of DNA molecules play a significant role in the sorption of the DNA molecules (page 5, lines 32-33).

With regard to claims 27 and 28, the metal of the metallic object is disclosed as being aluminum, titanium oxide, and zirconium oxide (page 4, lines 55-58).

**Comment [y1]:** U.S. PGPUB  
20040151907 evidences that TiO<sub>2</sub> and  
ZrO<sub>2</sub> are valve metals. Section [0010]

With regard to claim 29, while the claim further limits its parent claim 28, in that it further describes one of the members of the Markush group of said claim 28, claim 29 does not actively require that the metal is actually an intermetallic phase.

With regard to claims 30 and 32, the nucleic acid is single- or double- stranded DNA or RNA, or oligonucleotides (page 5, lines 29-30).

With regard to claims 35 and 36, the artisan discloses the labeling the hybridized DNA molecules (page 8, lines 30-41; page 10, line 57).

Therefore, the invention as claimed is clearly anticipated by Bitner.

Response to Arguments:

Applicants traverse the rejection.

Applicants state that, “[f]irst of all, there is no mention whatsoever in the entire reference relating to the 5'-terminal or 3' terminal ends being incorporated into the metal oxide layer or coating.” (page 6, Response).

It is respectfully submitted that this argument is not deemed persuasive for the following reasons.

Initially, the claims never require that the 5' or the 3' terminal ends be incorporated, but rather, 5' or 3' areas.

While not acquiescing to Applicants' assertion, it is respectfully submitted that the nucleic acid sorbed into the metal oxide surface of Bitner, would certainly be in the 5' or 3' "areas."

Secondly, it is respectfully submitted that Applicants' statement is an assertion without factual basis.

It is inconceivable that not a single nucleic acid produced by the method disclosed by Bitner is not capable of having its 5' or 3' end sorbed to the metal oxide layer, especially in face of their statement that their sorbed nucleic acids were free to hybridize (i.e., interact) with complementary nucleic acids (see page 14, lines 13-14).

Applicants also assert that the, “only disclosure” regarding the sorption of nucleic acid is found on page 3 (page 6, Response).

It is respectfully submitted Bitner discloses an actual working example of their substrate on page 14 and page 10.

Applicants also refer to Bitner's disclosure wherein the artisans state that “the phosphate groups of the DNA backbone may play a significant role in the sorption of the nucleic acids to the metal oxide.” (page 7, 2<sup>nd</sup> paragraph, Response).

Initially, Bitner's statement is not a conclusive statement not an absolute statement. Simply because the Bitner stated that DNA backbone may play a significant role in the sorption, such statement cannot be construed to absolutely state that the sorption only occurs in the backbone.

Secondly, as stated above, Applicants are not claiming nucleic acids which are embedded at their terminus, but rather in their 5' or 3' "area."

The argument is not found persuasive therefore.

With regard to Applicants statement regarding their invention, it is respectfully submitted that they are not relevant to the invention as claimed.

The rejection is proper and thus maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claim 31 under 35 U.S.C. 103(a) as being unpatentable over Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990) in view of Wengel et al. (U.S. Patent No. 6,670,461, issued December 30, 2003, filed on May 9, 2001), made in the Office Action mailed on August 28, 2007 is maintained for the reasons already of record.

Applicants do not present any new arguments for the present rejection in their Amendment received on November 28, 2007, but solely rely on the arguments which have been fully addressed above.

Therefore, the present rejection is maintained for the reasons already of record.

The Rejection:

The teachings of Bitner have already been discussed above.

Bitner does not disclose the use of nucleic acid compounds that have modification made thereto.

Wengel et al. disclose locked nucleic acids (LNA) which comprises ????? used in a diagnostic assay for detecting target nucleic acids with LNA probes via hybridization (column 2, lines 42-52).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bitner and the teachings of Wengel et al., thereby arriving at the claimed invention for the following reasons.

While Bitner does not explicitly disclose the use of other forms of nucleotide analogs which could be used as probes, one of ordinary skill in the art at the time the invention was made would have recognized that the advantage offered by LNA would have benefited said one of ordinary skill in the art to allow more stringent hybridization conditions, so as to preclude false positives in a hybridization assay of Bitner et al. The desire to increase stringency, as evidenced by Wengel et al., has been well-established in the art of nucleic acid hybridization detection. Hence, one of ordinary skill in the art would have been motivated to employ LNA nucleoside analogs into the immobilized nucleic acids of Bitner, thereby arriving at the invention as claimed.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

The rejection of claim 34 under 35 U.S.C. 103(a) as being unpatentable over Bitner, R.M. (EP 0 391 608 A2, published October 10, 1990) in view of Yabusaki et al. (WO 85/02628, published

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June 20, 1985) made in the Office Action mailed on August 28, 2007 is maintained for the reasons already of record.

Applicants do not present any new arguments for the present rejection in their Amendment received on November 28, 2007, but solely rely on the arguments which have been fully addressed above.

Therefore, the present rejection is maintained for the reasons already of record.

The Rejection:

The teachings of Bitner have already been discussed above.

Bitner does not disclose the hybridized nucleic acids are covalently bonded to the immobilized nucleic acids.

Yabusaki et al. disclose a method of forming covalent bonds between two hybridized nucleic acids by employing a nucleic acid which comprises cross-linking molecule that is covalently incorporated (page 3, lines 28-31; Abstract; page 32, lines 13-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the teachings of Bitner with the teachings of Yabusaki et al., thereby arriving at the claimed invention for the following reasons.

One of ordinary skill in the art, at the time the invention was made would have recognized that the formation of covalent bonds between the two hybridized nucleic acids would have allowed for stringent wash conditions so as to minimize false positive results in their hybridization assay, by forming a covalent bond between the immobilized nucleic acid and the hybridized nucleic acid of Bitner, thereby arriving at the claimed invention.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at combining the teachings given the fact that Yabusaki et al.



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employs the formation of covalent bonds between a probe and a target nucleic acid for the purpose of detection, demonstrating that cross-linking (for the formation of covalent bonds) could be made in solution, the condition of which is also used by Bitner.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

### ***Rejections, New Grounds – Necessitated by IDS***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,524,718 (herein ‘718 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 1-9 of the '718 patent is drawn to a metallic object consisting of a valve metal or valve metal alloy and a thin polyphase oxide coating comprising a metal oxide phase and a second phase, wherein said second phase is selected from biomolecules, such as oligomers (claim 2).

Therefore, the claims of the '718 patent renders the claims of the instant application obvious.

### ***Conclusion***

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on November 29, 2007 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot

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guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/  
Primary Examiner  
Art Unit 1637  
3/6/2008